

EXHIBIT 3

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE NORTHERN DISTRICT OF OHIO

3 EASTERN DIVISION

4 - - -

5 IN RE: NATIONAL : HON. DAN A.
6 PRESCRIPTION OPIATE : POLSTER
7 LITIGATION :
8 APPLIES TO ALL CASES : NO.
9 : 1:17-MD-2804
10 :
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12 - HIGHLY CONFIDENTIAL -

13 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

14 VOLUME I

15 - - -

16 April 17, 2019

17 - - -

18 Videotaped deposition of
19 THOMAS PREVOZNIK, taken pursuant to
20 notice, was held at the law offices of
21 Williams & Connolly, 725 12th Street,
22 Washington, D.C., beginning at 9:11 a.m.,
23 on the above date, before Michelle L.
24 Gray, a Registered Professional Reporter,
Certified Shorthand Reporter, Certified
Realtime Reporter, and Notary Public.

25 - - -

26 GOLKOW LITIGATION SERVICES
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1 system in use by wholesale drug
2 distributors for controlled substances,
3 do you see that reference that you just
4 read?

5 A. Yes.

6 Q. Is it fair to say then,
7 there was in fact at this point in time,
8 in 1998, a DEA-approved suspicious order
9 monitoring system for controlled
10 substances?

11 A. I would say no, because
12 there was never a -- DEA never had an
13 approved system. The system that the
14 statute requires and the regulations
15 require is the registrant is to design
16 and operate that system.

17 They come to us and they
18 say, here's our system, and we may have
19 discussions with them about it. So you
20 can have a great system in paper, but
21 when you implement it, are you actually
22 implementing what you say.

23 So that's part of our job,
24 when we go out there for schedule

1 investigation, is to look at that program
2 and are they doing what they're saying,
3 is it actually detecting suspicious
4 orders.

5 Q. So, Mr. Prevoznik, try to
6 listen to my question and answer it. I
7 realize that you would like to speechify
8 a little bit and get out your talking
9 points, but please restrain --

10 MR. FINKELSTEIN: Try not to
11 argue with the witness.

12 BY MS. MAINIGI:

13 Q. -- from doing that.

14 MR. FINKELSTEIN: You can
15 ask your questions. And you're
16 not here to abuse him.

17 BY MS. MAINIGI:

18 Q. So, Mr. Prevoznik, let's
19 back up. The DEA helped to write this
20 report, right?

21 A. Correct.

22 Q. And someone from the office
23 of diversion control at the DEA was in
24 fact the chair of the group that wrote

1 Q. And did you read far enough
2 in the report to see that there was, in
3 fact, an algorithm that was contained as
4 an exhibit to the report?

5 A. Do you have a page number?

6 Q. Sure: Bates Number 2247.

7 Did you review this page
8 previously?

9 A. Yes.

10 Q. Okay. And -- and this page
11 essentially contains a calculation or
12 algorithm for both List I chemicals and
13 Schedule II controlled substances,
14 correct?

15 A. Correct.

16 Q. Now, DEA did not require
17 distributors to use a particular
18 algorithm or metric to identify excessive
19 purchases of controlled substances,
20 correct?

21 A. Could you please repeat
22 that?

23 Q. DEA did not require that a
24 distributor use a particular calculation

1 or algorithm to identify excessive
2 purchases of controlled substances,
3 correct?

4 A. Correct.

5 Q. But, the DEA was aware that
6 certain registrants were using a
7 calculation or metric or algorithm to
8 identify an excessive purchase, correct?

9 MR. FINKELSTEIN: Objection.
10 Vague as to time.

11 THE WITNESS: I -- I just
12 want to make sure I'm clear on
13 this. We're talking about
14 excessive purchases or are we
15 talking about suspicious orders?

16 BY MS. MAINIGI:

17 Q. Well, right now I'm talking
18 about excessive purchase reports in this
19 time period.

20 Was the DEA aware that in
21 approximately the 1998 time period, that
22 distributors were using a particular
23 algorithm or calculation to identify
24 excessive purchases of controlled

1 Was the DEA aware that
2 certain employees had, in fact, blessed
3 the excessive purchase reporting systems?

4 MR. FARRELL: Objection.

5 Foundation.

6 THE WITNESS: I don't know
7 which employees you're speaking
8 of.

9 BY MS. MAINIGI:

10 Q. Just employees. Is -- is it
11 fair to say that the DEA did, in the late
12 '90s and early aughts, from time to time
13 review the reporting systems of
14 distributors and essentially give them a
15 yay or nay as to whether they thought
16 that the reporting system was suspicious?

17 MR. FARRELL: Objection.

18 Foundation.

19 MR. FINKELSTEIN: Objection.

20 Vague.

21 THE WITNESS: You lost me on
22 the last part.

23 BY MS. MAINIGI:

24 Q. Okay. Let me start over.

1 We -- we established before
2 that the DEA today does not review
3 reporting systems, right?

4 MR. FINKELSTEIN: Objection.

5 Mischaracterizes the witness's
6 testimony.

7 THE WITNESS: I mean, we --
8 we reviewed McKesson's, the new
9 one.

10 BY MS. MAINIGI:

11 Q. And you left it --

12 A. -- we reviewed it, we -- we
13 did not -- we --

14 MR. FINKELSTEIN: Let the
15 witness answer the question.

16 THE WITNESS: I don't know
17 what you mean by the term
18 "blessing it."

19 BY MS. MAINIGI:

20 Q. Okay.

21 A. Because as I had said
22 previously, that you -- you can write the
23 best system in the world, but if you
24 don't implement it and you don't stick to

1 it, it doesn't mean anything.

2 So that's part of our
3 review, when we go out and do schedule
4 investigations, is to review, are they
5 factually, in fact -- did -- is -- are
6 they operating a system that can detect a
7 suspicious order.

8 BY MS. MAINIGI:

9 Q. And that's something that
10 the DEA reviews periodically as part of
11 its auditing process, correct?

12 A. Correct.

13 Q. So as part of the audit
14 process, operating systems that are
15 designed to review suspicious orders are
16 reviewed by the DEA?

17 A. Well, it's not just the
18 schedule. I mean it could be a
19 pre-registration, somebody is coming on
20 and they have -- we have to go through
21 the whole public interest of, you know,
22 what do you have in place to operate and
23 detect a system. So it's not just a
24 schedule investigation. There are

1 schedule investigations that we follow
2 up, and we do that as well. So it comes
3 in -- it comes in various times that
4 we're going to review somebody's
5 operating system, whether we're on
6 schedule investigation, or whether we're
7 doing an investigation on a pharmacy or
8 something like that, where we're going to
9 look at how many SORs were submitted or
10 not submitted, or we're going to look at
11 the ARCOS data, how much did they buy.

12 We're going to look at
13 various things to make the determination
14 on what is going on.

15 Q. And if either in the
16 pre-registration process or in the audit
17 process the DEA determines that a
18 registrant's system is not adequately
19 detecting suspicious orders, is that
20 something that is conveyed to the
21 registrant?

22 A. Yeah, we -- we would tell
23 them, you need to add something.

24 Q. It's clear in the Rannazzisi

1 the characterization.

2 THE WITNESS: Nationwide,
3 correct.

4 BY MS. MAINIGI:

5 Q. Instead, one-off guidance
6 was perhaps provided in the context of
7 individual distributor meetings, correct?

8 A. Yes. Along with the MOAs
9 and the settlements that were done.

10 Q. And is there documentation
11 of what was said at the individual
12 distributor meetings?

13 A. It would be the PowerPoints
14 and the report -- after report.

15 Q. And this is an internal DEA
16 report?

17 A. Yes.

18 Q. And have you reviewed those
19 internal DEA reports for the purpose of
20 preparing for your testimony today?

21 A. Some of them.

22 Q. Now, does the DEA agree that
23 there's more than one way to design and
24 operate a system that can identify and

1 report suspicious orders?

2 A. Yes.

3 Q. And there's no single
4 feature that makes a suspicious order
5 monitoring system compliant, correct?

6 A. Correct.

7 Q. And the DEA leaves it up to
8 the registrant to design a system that
9 works with its own business model and
10 customer base, correct?

11 A. Correct.

12 Q. Does it matter to the DEA
13 whether a registrant reviews orders
14 manually or uses an automated system?

15 A. No, it doesn't matter.

16 Q. Other than requiring that
17 the report, suspicious order report
18 clearly indicate that the order is
19 suspicious, does DEA require suspicious
20 order reports to follow a particular
21 format?

22 A. That's correct.

23 Q. Let me ask the question
24 again. The DEA does not require

1 suspicious order reports to follow a
2 particular format, correct?

3 A. Well, I mean, they have to
4 follow what the regs say about unusual
5 size, unusual patterns, or frequency. I
6 mean, that's in there. We also ask that
7 the red flags and, you know, looking at
8 newspapers articles to see, you know,
9 what the overdoses are. You know, are
10 they looking at more than just the data,
11 because the data is only as good as --
12 you know, you can set the threshold too
13 high, you can set it too -- it's never
14 going to pick up something, or you're not
15 going to see patterns, because it's a new
16 customer that gets onboarded, and they're
17 already high, and you don't question it
18 or you don't look at it, you don't see
19 the population size, you don't see what's
20 their percentage of control versus not
21 control. I mean, there's a lot of
22 different factors that go in it. So
23 however they design it, they need to get
24 the big picture so that they truly know

1 what is their customer doing.

2 Q. Is there --

3 MR. FINKELSTEIN: Hang on.

4 Five minutes ago, I asked for a

5 break. We've been on the record

6 for more than an hour and a half.

7 Can you tell us when you are going

8 to be done?

9 MS. MAINIGI: Just a couple

10 more minutes.

11 BY MS. MAINIGI:

12 Q. Is the review -- is it fair

13 to say then that the identification of

14 suspicious orders can be a subjective

15 process?

16 MR. FINKELSTEIN: Objection.

17 Vague.

18 THE WITNESS: What do you

19 mean by "subjective"?

20 BY MS. MAINIGI:

21 Q. Well, do you understand the

22 meaning of the word "subjective"?

23 A. I'm asking you in terms of

24 this, what do you mean by subjective?

1 that this is outside the scope.

2 I'll let the witness answer for
3 now if you have understanding.

4 THE WITNESS: Yes.

5 BY MR. STEPHENS:

6 Q. Is it also true under -- you
7 testified earlier today about the C.F.R.
8 regulations, correct?

9 A. Correct.

10 Q. And under Title 21 -- or I'm
11 sorry, under 21 C.F.R. 1301.71(b), it's
12 true that the regulation regarding
13 suspicious order monitoring does not
14 require strict compliance, it requires
15 substantial compliance?

16 MR. FINKELSTEIN: Did you
17 mean 74?

18 MR. STEPHENS: It might be
19 74.

20 MR. FARRELL: 1301.74(b)?

21 MR. STEPHENS: Yes. No,
22 actually -- here. Let me just
23 mark it.

24 (Document marked for

1 identification as Exhibit

2 DEA-Prevoznik-13.)

3 BY MR. STEPHENS:

4 Q. I'll show the witness what's
5 been marked as Exhibit 13.

6 A. So, (b)?

7 Q. (B), right.

8 A. Okay.

9 Q. So (b) states substantial
10 compliance with the standards set forth,
11 right?

12 A. Yes.

13 Q. Okay. And that could be
14 deemed sufficient, correct?

15 A. Yes. That's what it says.

16 Q. It does not say strict
17 compliance, correct?

18 A. Correct.

19 Q. Like manufacturers and
20 distributors, DEA also considers doctors
21 who prescribe opioids to their patients
22 to be registrants?

23 A. Correct.

24 Q. Okay. The prescribing

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14 VOLUME II

15 - - -

16 April 18, 2019

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18 Continued videotaped
19 deposition of THOMAS PREVOZNIK, taken
20 pursuant to notice, was held at the law
21 offices of Williams & Connolly, 725 12th
22 Street, Washington, D.C., beginning at
23 8:16 a.m., on the above date, before
24 Michelle L. Gray, a Registered
Professional Reporter, Certified
Shorthand Reporter, Certified Realtime
Reporter, and Notary Public.

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1 speculating on that, but, yes.

2 BY MR. STEPHENS:

3 Q. Okay. I'd like to continue
4 by asking you some additional questions
5 about interpretation enforcement of
6 Title 21 U.S.C. 23, the regulations and
7 how those relate to the design of a
8 reasonable SOMs system. Okay?

9 A. Yes.

10 Q. Okay. So yesterday you --
11 you testified about different
12 distributors having different business
13 models, right?

14 A. Correct.

15 MR. FINKELSTEIN: Objection.

16 Scope. Characterization.

17 BY MR. STEPHENS:

18 Q. Is it fair to say that a
19 SOMs systems is not a one-size-all
20 proposition, one-size-fits-all
21 proposition?

22 A. Correct.

23 Q. And DEA understands that not
24 all registrants distribute opioids to the

1 same customers, right?

2 A. Correct.

3 Q. DEA understands that
4 registrants have different business
5 models?

6 A. Correct.

7 Q. And DEA expects that each
8 registrant will review its own business
9 model and design a SOM system that fits
10 its specific method of distribution?

11 MR. FINKELSTEIN: Objection.

12 Vague.

13 THE WITNESS: That's correct
14 as -- as per the regulations.

15 BY MR. STEPHENS:

16 Q. Okay. Some registrants
17 distribute to hospitals?

18 A. Correct.

19 Q. Some don't?

20 A. Correct.

21 Q. Some registrants distribute
22 to hospice centers?

23 A. Correct.

24 Q. Some don't?